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10/599,634	11/21/2006	Jozsef-Michel Geczy	06131	2059

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EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	PAPER NUMBER
1616	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,634	GECZY, JOZSEF-MICHEL	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 6-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/04/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 6-12 are pending examination.

Information Disclosure Statement

The information disclosure statement filed 10/04/2006 incorrectly lists the inventor names for 6,472,390 and 2003/045522 as Geczy and Stamler et al., respectively. This is incorrect as Geczy is the inventor of 2003/045522 and Stamler et al. is the inventor of 6,472,390.

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 6-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a method of preventing atherosclerosis comprising administering molsidomine in the form of a sustained-release solid oral composition effective over 24 hours.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention
2) the state of the prior art
3) the relative skill of those in the art
4) the predictability of the art
5) the breadth of the claims
6) the amount of direction or guidance provided
7) the presence or absence of working examples
8) the quantity of experimentation necessary

The nature of the invention.

The claimed invention relates to prevention of atherosclerosis by administering molsidomine.

The state of the prior art & predictability of the art

It is generally accepted that atherosclerosis can be treated but it cannot be prevented. Preventing atherosclerosis is highly unpredictable because it is dependent on the subject being treated and factors such as if they smoke, have high blood pressure, diabetes, high cholesterol or are obese. Furthermore, heredity and lifestyle effect and individuals susceptibility of developing atherosclerosis.

The breadth of the claims

The claims are extremely broad without limiting method steps that detail as to how the administration of the drug takes place.

The presence or absence of working examples

The specification provides no examples where atherosclerosis is prevented.

The quantity of experimentation necessary & relative skill in the art

To determine how to prevent atherosclerosis would require extensive experimentation for one skilled in the art.

Therefore, it would require undue experimentation to determine how to prevent atherosclerosis by administering molsidomine.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6, 8, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the written description requirement are (1) *level of skill and knowledge in the art,* (2) *partial structure,* (3) *physical and/or chemical properties,* (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function,* and the (5) *method of making.*

Claim 2 recites "wherein the sustained release oral composition effective over 24 hours has an in vitro dissolution rate, measured spectrophotometrically at 286 or 311 nm by the method described in the European Pharmacopoeia, 3rd Edition (or USP XXIV), at 50 rpm, in 500 ml of a 0.1 N HCl medium, at 37 degrees Celsius, of: 1-25% of molsidomine released after 1 hour, 20-35% of molsidomine released after 2 hours, 50-65%% of molsidomine released after 6 hours, >85% of molsidomine released after 18 hours, >90% of molsidomine released after 24 hours, the plasma peak of molsidomine obtained in vivo occurring 2.5 to 5 hours following the administration of said form, and having a value of between 25 and 40 ng/ml of plasma". However, it is unclear if applicants had possession of the claimed composition. Applicant has failed to properly

incorporate the composition into the specification by relying on a WIPO document.

University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (Fed.Cir. 2004), states that the description must convey what the compound is, not just what it does (see page 1895). A review of the language of the claim indicates that these claims are drawn to the action of composition rather than a particular structure. Therefore there are no structure disclosed in the claims and the written description requirement is not satisfied.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geczy (2003/0045522) in view of Grodzinska et al. (Journal of Drug Development, 1991).

Applicant's Invention

Applicant claims a method of prevention or attenuating development of atherosclerosis comprising administering molsidomine in a sustained release solid composition effective over 24 hours. Claims 7 and 8 specify the dosage contains 14-24 mg/dose. Claim 9 specifies the dosage as 16 mg/dose. Claims

11 and 12 specify the composition is administered to a patient suffering from angina pectoris.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Geczy teaches a sustained release oral galenical form of molsidomine for the treatment of all forms of angina for application in therapeutics(abstract). Claim 1 recites the drug form, wherein the sustained release oral composition effective over 24 hours has an in vitro dissolution rate, measured spectrophotometrically at 286 or 311 nm by the method described in the European Pharmacopoeia, 3rd Edition (or USP XXIV), at 50 rpm, in 500 ml of a 0.1 N HCl medium, at 37 degrees Celsius, of: 1-25% of molsidomine released after 1 hour, 20-35% of molsidomine released after 2 hours, 50-65%% of molsidomine released after 6 hours, >85% of molsidomine released after 18 hours, >90% of molsidomine released after 24 hours, the plasma peak of molsidomine obtained in vivo occurring 2.5 to 5 hours following the administration of said form, and having a value of between 25 and 40 ng/ml of plasma. The dosage is 14-24 mg/dose (Claim 2).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Geczy does not teach a method of prevention or attenuating development of atherosclerosis comprising administering molsidomine in a sustained release solid form. It is for this reason that Grodzinska et al. is joined.

Grodzinska et al. teach that atherosclerosis can be treated with molsidomine (abstract). The study showed improvement in the 20 male patients suffering from atherosclerosis during 2 and 4 weeks of treatment by activating the fibrinolytic system and inhibiting platelet aggregation.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Geczy and Grodzinska et al. to further include using molsidomine in a method of treating atherosclerosis. One would have been motivated to include the molsidomine because Grodzinska et al. teach that it is used to treat atherosclerosis by activating the fibrinolytic system and inhibiting platelet aggregation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner
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/Mina Haghighatian/
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